AcelRx Pharmaceuticals Receives $65 Million from the Partial Sale of Zalviso™ European Royalties and Commercial Milestones to PDL BioPharma

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REDWOOD CITY, Calif., Sept. 21, 2015 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, today announced the monetization of the expected royalty stream from the sales of Zalviso™ (sufentanil sublingual tablet system) in the European Union by its commercial partner Grunenthal GmbH. Gross proceeds from the sale are $65 million from PDL BioPharma (NASDAQ: PDLI). Specifically, PDL will receive 75% of the European royalties under the Grunenthal license as well as 80% of the first four commercial milestones, subject to a capped amount. AcelRx will receive 25% of the royalties, 20% of the first four commercial milestones, 100% of the remaining commercial milestones and all development milestones, including a potential $15 million payment for the approval of the Zalviso MAA. The proceeds from the transaction will provide AcelRx with additional operating capital, which will be used for general corporate purposes, including regulatory activities associated with ARX-04 and Zalviso.

Timothy E. Morris, chief financial officer of AcelRx Pharmaceuticals, commented, "This transaction provides AcelRx with significant capital in a non-dilutive manner. It will increase our estimated cash at year end to over $100 million and should provide sufficient capital to complete regulatory submissions for ARX-04 in the U.S. and Europe, and to conduct limited additional work on Zalviso, if needed, in preparation for re-submitting a New Drug Application to the U.S. Food and Drug Administration."

The transaction will be treated as a sale for tax purposes. AcelRx has established a wholly owned subsidiary, ARPI LLC, to facilitate the transaction. Credit Suisse acted as sole structuring and financial advisor to AcelRx in connection with the transaction. AcelRx was represented by Cooley LLP, PDL by Gibson, Dunn & Crutcher LLP and Credit Suisse by Cadwalader, Wickersham & Taft LLP.

Separately, concurrently with the closing of the royalty monetization, AcelRx amended its existing credit facility with Hercules Technology Growth Capital, Inc. (NYSE: HTGC), which includes an interest only period from October 1, 2015 through March 31, 2016 (with the potential for further extension to September 30, 2016 upon satisfaction of certain conditions). Loans under the credit facility will mature on October 31, 2017. In connection with the amendment, AcelRx reduced the exercise price of warrants previously issued to Hercules in connection with the credit facility.

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. In the US, the Company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso™ (sufentanil sublingual tablet system) for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil sublingual, a high therapeutic index opioid, through a disposable, pre-filled, single-dose applicator (SDA). AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and will be advancing ARX-04 into a study in emergency room patients in 2015. Zalviso delivers 15 mcg sufentanil sublingual tablets through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, the Company received a Complete Response Letter (CRL) on July 25, 2014. The FDA has requested an additional clinical study prior to the resubmission of the Zalviso NDA.

The Company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

Forward Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to potential milestones payments under the Grunenthal agreement and expected royalty stream from the sales of Zalviso in the European Union by Grunenthal; future financial results, including anticipated cash balance at year-end 2015 and use of proceeds from the sale of royalty and milestone payments to PDL BioPharma; potential extension of the interest-only period under amended credit facility with Hercules Technology Growth Capital, Inc.; the process and timing of anticipated future development of AcelRx's product candidates, including Zalviso and ARX-04, including the timing and potential additional clinical work necessary for resubmission of Zalviso NDA to the FDA; potential approval of Zalviso and the timing of commercial launch of Zalviso in Europe; and the anticipated timing of the emergency room study for ARX-04. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso and ARX-04, in the United States and Europe; any delay of the European Commission's decision regarding Zalviso; inability to successfully manufacture Zalviso to meet the requirements of Grunenthal and potential delays in the timing of the European launch; AcelRx's ability to receive milestones and royalty payments under the Grunenthal agreement; the market potential for its product candidates, including Zalviso and ARX-04, in the United States and Europe; its ability to timely resubmit Zalviso NDA to the FDA and to receive regulatory approval for Zalviso, that fact that FDA may dispute or interpret differently positive clinical results obtained to date from the pivotal Phase 3 SAP301 ambulatory surgery study of ARX-04; its ability to obtain sufficient financing to receive regulatory approval for and commercialize Zalviso in the United States and Europe, and complete Phase 3 clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the planned Phase 3 ARX-04 emergency room trial; the accuracy of AcelRx's estimates regarding expenses, capital requirements and use of proceeds from the sale of royalty and milestone payments to PDL BioPharma; and other risks

detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on August 4, 2015. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

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